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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/319,156	11/02/1999	GLAUCIA PARANHOS-BACCALA	103514	2490
25944 7590 03/27/2008 OLIFF & BERRIDGE, PLC P.O. BOX 320850 ALEXANDRIA, VA 22320-4850				
EXAMINER				
PARKIN, JEFFREY S				
ART UNIT		PAPER NUMBER		
1648				
MAIL DATE		DELIVERY MODE		
03/27/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

## Application No.

09/319,156

## Applicant(s)

PARANHOS-BACCALA ET AL.

## Examiner

Jeffrey S. Parkin, Ph.D.

## Art Unit

1648

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1, 7, 9, 14, 15, 26, 28-30, 36-38, 40-42, 45-47, 49-51 and 60-66 is/are pending in the application.
- 4a) Of the above claim(s) 26 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 65 and 66 is/are allowed.
- 6) ☒ Claim(s) 1, 7, 9, 14, 15, 28-30, 36-38, 40-42, 45-47, 49-51, and 60-64 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Final Drawing (PTO-846)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

Serial No.: 09/319,156

Applicants: Paranhos-Baccala, G., et al.

Docket No.: 103514

Filing Date: 11/02/99

### **Supplemental Office Action**

#### ***Status of the Claims***

Acknowledgement is hereby made of receipt and entry of the communication filed 07 August, 2007. Claims 1, 7, 9, 14, 15, 26, 28-30, 36-38, 40-42, 45-47, 49-51, and 60-66 are pending in the instant application. Claim 26 stands withdrawn from further consideration by the examiner, pursuant to 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention (see the restriction requirement mailed 16 February, 2001). This application contains claim 26 drawn to an invention non-elected with traverse. A complete response to the final rejection must include cancellation of non-elected claims or other appropriate action (refer to 37 C.F.R. § 1.144 and M.P.E.P. § 821.01). Claims 1, 7, 9, 14, 15, 28-30, 36-38, 40-42, 45-47, 49-51, and 60-66 are currently under examination.

#### ***35 U.S.C. § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 7, 14, 15, 28-30, 36-38, 45-47, 49-51, and 60-64 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Two separate requirements are set forth under this statute: (1) the claims must set forth the subject matter that applicants regard as their invention; and (2) the claims must

particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant. The claims have been amended to recite sequences "derived from" or "equivalent to" the sequences of interest. These limitations are confusing because the precise structural characteristics of the claimed nucleic acids is not readily manifest. For instance, what constitutes a nucleotide sequence that is "equivalent to" a sequence of SEQ ID NO.: 6, 9, 12, or a sequence encoding the polypeptide of SEQ ID NO.: 10? A sequence either has the same nucleotide/amino acid sequence or it is different. What are the structural differences between one of the aforementioned sequences and an "equivalent" sequence? In what context are the sequences equivalent? The reference to "derived from" is also confusing since the precise structural characteristics are not readily manifest. Are the claims simply directed toward nucleotide sequence variants of the parent sequences or are the claims directed toward modified polynucleotides (i.e., with an attached label; modified backbone; etc.)? Appropriate clarification and correction are required. Applicants may obviate the rejection by simply directing the claims toward the parent sequences of interest or sequences that display the desired degree of genetic relatedness (i.e., ... (i) full-length sequences set forth in SEQ ID NO.: 6, SEQ ID NO.: 9, and SEQ ID NO.: 12; (ii) sequences complementary to the full-length sequences set forth in (i); (iii) sequences that display at least 70% nucleotide sequence identity with the sequences of (i) or (ii), for every 100 contiguous nucleotides examined...).

**35 U.S.C. § 112, First Paragraph**

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

*Written Description*

Claims 1, 7, 9, 14, 15, 28-30, 36-38, 40-42, 45-47, 49-51, and 60-64 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 43 U.S.P.Q.2d 1398, (Fed. Cir. 1997). *Fiers v. Revel Co.*, 984 F.2d 1164, 25 U.S.P.Q.2d 1601, (Fed. Cir. 1993). *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 U.S.P.Q.2d 1016, (Fed. Cir. 1991). *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 296 F.3d 1316, 63 U.S.P.Q.2d 1609, (Fed. Cir. 2002). *Univ. of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916, 920, 69 U.S.P.Q.2d 1886, (Fed. Cir. 2004). *In re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). *In re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). *University of Rochester v. G. D. Searle & Co., Inc.*, 358 F.3d 916, 69 U.S.P.Q.2d 1886 (C.A.F.C. 2004).

The claims are directed toward isolated polynucleotides comprising the full-length sequences set forth in SEQ ID NOS.: 6, 9, and 12. Appropriately drafted claim language directed toward these full-length sequences, and full-length

complementary sequences, would be acceptable. However, additional claim embodiments specify derivative or equivalent sequences obtained from these parent sequences that display varying degrees of genetic relatedness (e.g., 70%, 80%, 90%, and 95%) with every 100 contiguous nucleotides. The claims are also directed toward polynucleotide sequences encoding a polypeptide comprising SEQ ID NO.: 10, wherein said polypeptide displays varying degrees of genetic relatedness (e.g., 70%, 80%, 90%, and 95%) for every 30 amino acids (or 90 nt) considered. The nucleotide sequences of interest encompass 635 nt, 1481 nt, and 1329 nt (SEQ ID NOS.: 6, 9, and 12, respectively). The polynucleotides encoding SEQ ID NO.: 10 (493 aa) must be a minimum of 1479 nt. The claims do not require that the full-length polynucleotides display the degree of genetic relatedness claimed, only every 90-100 nucleotides. Thus, the nucleic acids of interest could encompass 100 nucleotides at the 5' end that are 100% genetically identical, but the remaining portion of the sequence could be entirely unrelated. As previously set forth, to satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Vas-Cath, Inc., v. Mahurkar*, 935 F.2d at 1563, 19 U.S.P.Q.2d at 1116. The issue raised in this application is whether the original application provides adequate support for the broadly claimed genus of nucleic acids.

An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565,

1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997). The claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the biomolecule of interest. *In re Bell*, 991 F.2d 781, 26 U.S.P.Q.2d 1529 (Fed. Cir. 1993). *In re Deuel*, 51 F.3d 1552, 34 U.S.P.Q.2d 1210 (Fed. Cir. 1995). A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 U.S.P.Q.2d 1895, 1905 (Fed. Cir. 1995). The court noted in this decision that a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not reasonably lead those skilled in the art to any particular species.

An applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical

and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. For some biomolecules, examples of identifying characteristics include a nucleotide or amino acid sequence, chemical structure, binding affinity, binding specificity, and molecular weight. The written description requirement may be satisfied through disclosure of function and minimal structure when there is a well-established correlation between structure and function. Without such a correlation, the capability to recognize or understand the structure from the mere recitation of function and minimal structure is highly unlikely. In the latter case, disclosure of function alone is little more than a wish for possession; it does not satisfy the written description requirement. *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1566, 43 U.S.P.Q.2d 1398, 1404, 1406 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998). *In re Wilder*, 736 F.2d 1516, 1521, 222 U.S.P.Q. 369, 372-3 (Fed. Cir. 1984). Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention.

Moreover, where claims directed toward nucleic acids are concerned, legal precedence also clearly dictates that conception of a chemical compound (e.g., a DNA molecule) is not achieved until reduction to practice has occurred (*University of California v. Eli Lilly*, 119 F.3d 1559, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997); *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 U.S.P.Q.2d 1016-1031 (C.A.F.C. 1991); *Fiers v. Sugano*, 25



U.S.P.Q.2d 1601-1607 (C.A.F.C. 1993); *In re Bell*, 26 U.S.P.Q.2d 1529-1532 (C.A.F.C. 1993); *In re Deuel*, 34 U.S.P.Q.2d 1210-1216 (C.A.F.C. 1995)). In *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.* the court concluded that "It is not sufficient to define it solely by its principal biological property, e.g., encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property. We hold that when an inventor is unable to envision the detailed constitution of a gene so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has occurred, i.e., until after the gene has been isolated." The significance of conception and reduction to practice was further addressed by the court in *Fiers v. Sugano* where it was emphasized that "Conception is a question of law, reviewed *de novo* on appeal, and if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated; thus, regardless of complexity or simplicity of method of isolation employed, conception of DNA sequence, like conception of any chemical substance, requires definition of that substance other than by its functional utility." Thus, the courts have emphasized that the inventor must clearly and unambiguously identify the salient characteristics and properties of any given claimed nucleotide sequence. It is not sufficient to provide a vague reference to the biological activity of any given nucleotide sequence or some generic method of obtaining it.

The disclosure describes the isolation and characterization of a novel human retrovirus that may be associated with multiple

sclerosis. A molecular clone was obtained and the purported nucleotide sequence of the *env* gene ascertained. Thus, the skilled artisan would reasonably conclude that applicants were in possession of those particular clones containing SEQ ID NOS.: 6, 9, and 12. However, the broadly recited claim language directed toward fragments, derivatives, or equivalents is wholly unsupported by the disclosure. The sequences of interest are 635 nt, 1481 nt, and 1329 nt in length (SEQ ID NOS.: 6, 9, and 12, respectively). The polynucleotides encoding SEQ ID NO.: 10 (493 aa) must be a minimum of 1479 nt. The claims only stipulate that these sequences have the recited genetic relatedness (e.g., 70%, 80%, 90%, and 95%) for every stretch of 100 nucleotides. Thus, for each of the identified sequences as many as 535 nt, 1381 nt, and 1229 nt do not require any particular structural information. This genus of variants encompasses an inordinate number of species. For instance, if the degree of genetic relatedness is extended to the full-length sequences (not just a 100 nt stretch), at 70% genetic relatedness sequence six would encompass  $9 \times 10^{260}$  variants, sequence nine  $9 \times 10^{606}$  variants, and sequence 12  $2 \times 10^{544}$  variants. Even if the degree of genetic relatedness is extended to 95%, the claims would still encompass the following number of variants for each sequence:  $9 \times 10^{71}$ ,  $6 \times 10^{164}$ , and  $2 \times 10^{147}$ , respectively.<sup>1</sup> The disclosure only provides nucleotide sequence data from a single MSRV isolate. Moreover, the disclosure fails to identify any critical molecular determinants modulating the functional activities of the Env glycoprotein. It has been well-documented in the prior art that single or multiple amino

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<sup>1</sup> These calculations were based upon the following equation:  $(3^{sl} - 1) / (n - 1)$ . *n* equals the number of nucleotides that can be substituted and *sl* equals the sequence length of interest.

acid substitutions, additions, or deletions can have profound influences on protein activity. Therefore, the skilled artisan has been asked to guess as to which of the various nucleic acids might retain the desired activity. Finally, perusal of the specification fails to lead the skilled artisan to any particular sequence.

Furthermore, the court concluded in *In re Gosteli* that the disclosure of a single species is insufficient support for claims directed toward a broader genus. *In re Gosteli*, 872 F.2d 1008, 1010, 10 U.S.P.Q.2d 1614, 1616 (Fed. Cir. 1989). The importance of providing detailed structural information for a representative number of species was also emphasized by the court in *Univ. of Rochester* who stated that the disclosure contained in the application "just represents a wish, or arguably a plan, for obtaining the DNA," and that "it does not indicate that [the applicant] was in possession of the DNA." *Id.* at 1171. The court added that a description of DNA requires "a precise definition, such as by structure, formula, chemical name, or physical properties...." As referenced above, the court said that "[c]laiming all DNA's that achieve a result without defining what means will do so is not in compliance with the description requirement; it is an attempt to preempt the future before it has arrived." *University of Rochester v. G.D. Searle & Co.*, 68 U.S.P.Q.2d 1424 (D.C. W.N.Y. 2003).

#### *Response to Arguments*

Applicants' submit that a structural/functional nexus is only one of the elements required to demonstrate possession of a genus. Other relevant identifying characteristics may be employed as well. While other characteristics may be employed to demonstrate possession, none of them are particularly germane

to the claimed sequences of interest. Moreover, the disclosure fails to provide any nexus between the structural and functional properties of the claimed nucleic acids. Presumably these sequences are directed toward the *env* gene of a retrovirus associated with multiple sclerosis (MS). However, the disclosure fails to provide any detailed characterization of these sequences. The disclosure fails to set forth any variants of interest. Nothing in the disclosure leads the inventor to any particular species. Moreover, single or multiple amino acid additions, deletions, or substitutions can abrogate Env function. However, the disclosure is silent pertaining to those substitutions that will retain the native configuration and properties of the wildtype viral envelope.

Applicants also rely upon three Board decisions in support of their arguments: *Ex Parte Bandeman* (Appeal No. 2004-2319), *Ex Parte Au-Young* (Appeal No. 2003-1817), and *Ex Parte Sun* (Appeal No. 2003-1993). These cases all involved nucleic acid claims involving differing degrees of genetic relatedness. The Board agreed with Appellants' arguments in these cases and suggested that even a single species was sufficient to put Appellants in possession of the broadly claimed genus of compounds. The examiner was unable to determine if these decisions have been published and made precedential. Moreover, it does not appear that all of the same arguments were advanced in those applications. Thus, there are issues raised in this application that were not previously considered by the Board in these other decisions. Applicants are directed toward a recent published decision that is directly relevant, *Ex parte Kubin*, 83 U.S.P.Q.2d 1410 (Bd. Pat. App. & Int. 2007). The claims in this application were directed toward nucleic acids encoding a protein that was 80% genetically related to the parent sequence

(aa 22-221). The court concluded that these claims were not adequately supported by a disclosure of two species (both of which were identical to aa 22-221). Thus, this decision would seem to contradict applicants' assertions. The Board concluded that a "Specification in application claiming nucleotide sequences encoding natural killer cell activation inducing ligand ("NAIL") polypeptide does not contain written description sufficient to show that applicants had possession of full scope of claimed invention at time application was filed, since claim at issue is directed to genus of polynucleotides encoding polypeptides "at least 80% identical to amino acids 22-221 of SEQ ID NO:2" binding to "CD48," which is membrane glycoprotein found on cells of hematopoietic origin, since applicants have sequenced two nucleic acids falling within scope of claim, and three fusion proteins having nucleotide sequences that would fall within scope of claim, but none of these sequences varies amino acids 22-221 of NAIL, and sequences thus are not representative of genus, since applicants have also described how to make and test other sequences within claim, but they have not described what domains of those sequences are correlated with required binding to CD48, and thus have not described which of NAIL's amino acids can be varied and still maintain binding, and since applicants' specification therefore would not have shown possession of sufficient number of sequences falling within their potentially large genus to establish possession of that genus; absent correlation between structure and function, claim does little more than define invention by function, which is insufficient to satisfy written description requirement." These facts are similar to those in the instant application wherein a novel MS-associated retroviral env gene has been identified. However, the disclosure fails to provide any

detailed functional guidance pertaining to the properties of the Env and fails to provide any variant sequences. Accordingly the rejection is proper and maintained.

**35 U.S.C. § 102(b)**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7, 14, 15, and 60 stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by Boehringer Mannheim (1994). Applicants' submit that the claim amendments are sufficient to obviate the rejection. The examiner does not concur with this assessment. The claims are still directed toward "complementary" sequences that do not specify any size constraints. Thus, the claims could encompass as few as two nucleotides. The Boehringer Mannheim publication discloses DNA labeling kits comprising a mixture of hexanucleotides that contains all possible six-nucleotide sequences. Accordingly, this teaching meets all of the claimed limitations. Applicants may obviate the rejection by directing the claim language toward "full-length" complementary sequences or something similar thereto.

**Allowable Subject Matter**

The previous indication that claims 65 and 66 were allowable was based upon the examiner's assumption that the term

"complementary" referenced full-length complementary sequences. However, in order to avoid any confusion or ambiguity on the record regarding the interpretation of these claims, it is suggested that applicants either amend the claim language appropriately (i.e., a full-length complementary sequence) or provide a statement concurring with the examiner's interpretation.

***Action Is Final, Necessitated by Amendment***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

***Correspondence***

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Bruce R. Campell, Ph.D., can be reached at (571) 272-0974. Direct general status inquiries to the Technology Center 1600

receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Applicants are reminded that the United States Patent and Trademark Office (Office) requires most patent related correspondence to be: a) faxed to the Central FAX number (571-273-8300) (updated as of July 15, 2005), b) hand carried or delivered to the Customer Service Window (now located at the Randolph Building, 401 Dulany Street, Alexandria, VA 22314), c) mailed to the mailing address set forth in 37 C.F.R. § 1.1 (e.g., P.O. Box 1450, Alexandria, VA 22313-1450), or d) transmitted to the Office using the Office's Electronic Filing System. This notice replaces all prior Office notices specifying a specific fax number or hand carry address for certain patent related correspondence. For further information refer to the Updated Notice of Centralized Delivery and Facsimile Transmission Policy for Patent Related Correspondence, and Exceptions Thereto, 1292 Off. Gaz. Pat. Office 186 (March 29, 2005).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

/Jeffrey S. Parkin, Ph.D./  
Primary Examiner, Art Unit 1648

22 March, 2008



**Application Number**

Application/Control No.

09/319,156

Examiner

Jeffrey S. Parkin, Ph.D.

Applicant(s)/Patent under  
Reexamination

PARANHOS-BACCALA ET AL.

Art Unit

1648